Decision Memo for Arthroscopy for the Osteoarthritic Knee (CAG-00167N)

Decision Summary

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CMS has also determined that the evidence is adequate to conclude that arthroscopic debridement is not reasonable and necessary for patients presenting with knee pain only or with severe osteoarthritis (Outerbridge classification III or IV); therefore, we intend to issue a national noncoverage determination. All other indications of debridement for patients with osteoarthritis of the knee will remain at contractor discretion.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

To: Administrative File CAG: (#00167N)
Arthroscopy for the Osteoarthritic Knee

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Subject: National Coverage Determination Memorandum for Arthroscopy for the Osteoarthritic Knee

Date: July 3, 2003

I. Decision

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II. Background

On October 10, 2002, CMS began a national coverage determination process for arthroscopic lavage and/or debridement for the treatment of the osteoarthritic knee.

There are more than one hundred types of arthritis affecting millions of people.[1] Osteoarthritis (OA), one type of arthritis, is a chronic, often painful joint disease. It is the most common joint disease in the United States and affects more than 20 million people.[2] Among the elderly population in developed countries, knee OA is the leading cause of chronic disability.[3] At this time the etiology of arthritis is not known. Some risk factors have been identified and include older age, obesity, major trauma to the joint area, and repetitive joint use. OA is also more common among older women. Examining the Medicare database for outpatient claims, CMS found that for those beneficiaries with a primary diagnosis code of OA of the lower leg, ankle, and foot, there were 24,516 allowed services for knee arthroscopy performed for the diagnosis of osteoarthritis in the year 2001.[4]

OA may occur in any joint and often with an insidious onset. Early in the disease process, joints may ache after physical work or exercise. The most common joints affected are the hands, knees, hips, and spine. Some warning signs of OA are “steady or intermittent pain in a joint, stiffness in a joint after getting out of bed or sitting for a long time, swelling or tenderness in one or more joints, a crunching feeling or the sound of bone rubbing on bone.”[5]

Pathology

OA affects the cartilage, a slippery tissue covering the ends of bones in a joint. When healthy, cartilage allows the bones to glide over one another in the joint space as well as absorbing the shock of movement. As OA advances, the joint surface thins, the cartilage softens, and clefts begin to develop.[6] In essence, the surface layer of cartilage breaks down and wears away, resulting in remodeling, hypertrophy (overgrowth) and, eventually, sclerosis.[7] Bone spur development is also a potential.[8] Movement can then be restricted due to disruption of the contour of the joint. Patchy synovitis (inflammation of the synovium), and thickening of the joint capsule may result in further movement restriction, and finally, small pieces of bone and cartilage may break off and float inside the joint space causing further pain and damage.[9]

The correlation between an individual's (self-reported) joint pain and the pathologic severity of their osteoarthritis is poor. One might have significant changes radiographically and have mild to no pain. In addition, patients with the same radiologic severity of OA may not experience or report having similar levels of pain.

Based on the American College of Rheumatology (ACR) criteria, a patient may be diagnosed with OA of the knee if they have pain and at least five of the following:[10]

- Over 50 years of age
- Less than 30 minutes of morning stiffness
- Crepitus (noisy, grating sound) on active motion
- Bony tenderness
- Bony enlargement
- No palpable warmth of synovium
- ESR<40mm/hr
- Rheumatoid Factor < 1:40
- Synovial fluid signs

Treatment

Currently, there is no known cure for OA of the knee. Reducing pain, maintaining mobility, and minimizing disability are the goals of OA treatment. Treatment modalities progress from nonpharmacologic measures,[11] to drug therapy (oral and injectable), to surgery if necessary.

Drug therapy may begin with simple pain relievers[12] and progress to intermittent corticosteroid injections. Newer drugs, such as hyaluronic acid, which are engineered to resemble normal joint fluid, may be injected. In addition to drug therapy, physical or occupational therapy to restore joint movement and increase strength are useful in treatment of OA. Short periods of rest or non-weight bearing on the affected joints in addition to application of heat or cold may reduce pain.[13] Finally, weight loss has been found to be a useful treatment to reduce extra stress on weight bearing joints.

When medical management fails, surgery is often indicated. Joint arthroscopy, which involves direct visualization of the joint by a fiber-optic viewing instrument, is the least invasive surgical procedure and often involves debridement and lavage. Knee reconstruction may include osteotomy[14] or arthroplasty.[15] The most invasive treatment for OA is a total knee replacement (TKR). This coverage analysis and the subsequent determination is limited to knee arthroscopy rather than addressing the other forms of treatment described previously.

For the purposes of this decision memo, knee arthroscopy for OA may include both debridement and lavage. Debridement is often performed to reduce pain and mechanical symptoms and improve functioning in the patient with osteoarthritis of the knee. Debridement has been referred to as “a blanket term that may cover many types of arthroscopic surgery and is almost impossible to quantify.”[16] It may include but is not limited to variable amounts of the following treatments: partial synovectomy,[17] decompression and resection of plicae/adipose tissue, partial menisectomy,[18] chondroplasty,[19] loose body removal, and/or osteophyte removal. In clinical practice, debridement is generally performed with low volume lavage or washout. For purposes of this decision memo, debridement, when used alone or not otherwise specified, may include low volume lavage or washout. Lavage alone may involve either large or small volume saline irrigation of the knee by arthroscopy. It is generally performed to reduce pain and improve functioning. Current practice does not recognize the benefit of lavage alone for the reduction of mechanical symptoms.

III. History of Medicare Coverage

There is currently no national Medicare coverage decisions related to arthroscopic lavage and/or debridement of the osteoarthritic knee. Therefore, coverage for these procedures is determined by the Medicare contractors who administer the program for each region. No local medical review policy exists that limit the coverage or arthroscopy for the osteoarthritic knee.

For an item or service to be covered by the Medicare program it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. Arthroscopy for the treatment of the osteoarthritic knee may be included in several Medicare benefit categories, including:

§ 1861 (b)(3) inpatient hospital services
§ 1861 (s)(1) physician services
§ 1861 (s)(2)(B) hospital services “incident to” physicians’ services rendered to outpatients

Payment codes exist for which this procedure has been reimbursed.

IV. Timeline of Recent Activities

An RCT conducted by Moseley et al. (2002) concluded that arthroscopic lavage and/or debridement in patients with painful osteoarthritis of the knee refractory to medical management is no better than placebo surgery at relieving pain and improving function. After discussions with the clinical investigators, the orthopedic community, and other interested parties, CMS decided to evaluate the body of the scientific evidence related to this issue to determine the indications for which arthroscopic lavage and/or debridement for the treatment of the osteoarthritic knee is reasonable and necessary for Medicare patients.

October 17, 2002	Initiation of formal review process and timeline posted on CMS website.
December 9, 2002	CMS met with representatives from the American Academy of Orthopaedic Surgeons (AAOS), American Association of Hip and Knee Surgeons/Knee Society (AAHKS), American Orthopaedic Society of Sports Medicine (AAOSSM), and Arthroscopy Association of North America (AANA) on November 25, 2002, to discuss the appropriate indications for arthroscopy of the osteoarthritic knee. At the conclusion of this meeting, the AAOS and other specialty societies agreed to provide additional information detailing the specific appropriate indications for arthroscopic surgery for the osteoarthritic knee, including the scientific evidence and clinical rationale supporting each of these indications.
January 30, 2003	CMS met with AAOS senior staff and clinicians on January 30, 2003, to discuss the report "Arthroscopic Surgery and Osteoarthritis of the Knee" [PDF, 71KB] submitted on behalf of the AAOS, AAHKS, AOSSM, and AANA to CMS on January 20, 2003.
February 21, 2003	AAOS report "Arthroscopic Surgery and Osteoarthritis of the Knee" [PDF, 71KB] posted on the CMS website.

V. FDA Status

Arthroscopes are generally "Non-Significant Risk Devices," as defined in 21CFR 812.3(m). The equipment and supplies used for arthroscopic lavage and debridement of the osteoarthritic knee have received approval and/or 510 (k) clearance from the Food and Drug Administration.

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of reasonable and necessary. The evidence may consist of external technology assessments, internal review of published and un-published studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments. Regardless of source, we assess the methodological rigor of the clinical evidence.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical questions relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention’s risks and benefits.

The issues presented here represent a broad discussion of the methodological issues we consider when reviewing clinical evidence, particularly clinical studies. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. The goal of our determination process is to assess net health outcomes, and we are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

An intervention is not reasonable and necessary if its risks outweigh its benefits. For all determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. The direction, magnitude and consistency of the risks and benefits across studies are important considerations. Based on the analysis of the strength of the evidence, CMS assesses whether an intervention or technology's benefits to Medicare beneficiaries outweigh its harms.

VII. Evidence

A. Introduction

Debridement and lavage is used for treatment of OA of the knee as a method to alleviate pain and symptoms, improve functioning, and to delay the need for total knee replacement (TKR). Because artificial knees have a finite lifetime of up to 15 years, the avoidance or delay of TKR is particularly important for younger patients.[20] Therefore, it is important to understand the impact of lavage and debridement for the reduction of pain[21] and improvement of function[22] for those with osteoarthritis.

CMS is concerned with the impact of a reduction of pain and improved function by arthroscopic lavage and debridement for patients with an osteoarthritic knee. These outcomes are often used as indications for arthroscopic debridement and lavage. Therefore, a significant reduction in either would be beneficial to the patient and, thus, are the most appropriate health outcomes for CMS to examine.

Our evidence summary and analysis focused on answering the following questions:

- Is the evidence adequate to determine the impact of arthroscopic lavage alone on reduction of pain and improvement of function?
- Is the evidence adequate to determine the impact of arthroscopic debridement on reduction of pain and improvement of function?
- Is the evidence adequate to determine the impact of either debridement or lavage for a subpopulation of those with OA?

The following summary of evidence section represents the body of evidence reviewed for this decision analysis. This includes the following: 1) peer-reviewed articles identified in both a literature search by CMS as well as articles submitted by the AAOS, 2) evidence-based guidelines; and 3) position statements by the AAOS and ACR.

Measures of Clinical Treatment Outcomes for Arthroscopy for the Osteoarthritic Knee

In reviewing the clinical evidence of the impact of lavage and debridement for the osteoarthritic knee, CMS noted the wide array of instruments used to evaluate pain, functioning, and impact of arthroscopy. Instruments used to measure outcomes for osteoarthritis of the knee and those CMS encountered during our analysis of the evidence can be found summarized in Appendix A.

This section briefly describes the most commonly found clinical instruments in the articles reviewed. These instruments measure: the severity of the disease (Outerbridge); pain (Knee-Specific Pain Scale (KSPS) and visual analog scales (VAS)); functioning (Short-Form General Health Survey (SF-36) and Lysholm scale); and changes in health status after arthroscopy (Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC), Lequesne Index of Severity for OA of the Knee (ISOA Knee). and Arthritis Impact Measurement Scales (AIMS-2)).

The most commonly used instrument to classify the severity of osteoarthritis in study patients was the Outerbridge scale. The Outerbridge scale classifies the articular degeneration of the knee by compartment in four grades. Grade I refers to softening or blistering of the articular cartilage. Grade II describes fragmentation or fissuring in an area <1cm, while those with an area >1cm is considered Grade III. Finally, Grade IV refers to cartilage erosion down to the bone. This classification system was used for the purposes of patient selection and stratification in many of the articles used.[23]

Three of the most common measures of pain were the KSPS and VAS. The KSPS was used to measure the primary outcome of interest, pain, in the Moseley (2002) study. This scale measures pain using a 12-item self-reported instrument. Scores for this scale ranged from 0 to 100 with higher scores indicating greater pain. At the time of publication of Moseley et al (2002) no studies had been published validating this instrument. A VAS asks the respondent to rate their experience of pain using a 10 cm horizontal scale. This scale is not specific to knee pain, but has proven validity and reliability.[24]

The SF-36 and its pain sub-scale were also commonly cited instruments to measure outcomes from arthroscopy. The SF-36 has been well validated and found to be reliable in patients with osteoarthritis.[25] Functioning is assessed through thirty-six items and nine scales where a greater score refers to greater functioning. Another scale used to measure functioning in the literature reviewed was the Lysholm scale. This scale asks respondents whether they limp; experience locking, instability, pain, and swelling; and whether they have problems squatting, climbing stairs, or need support. Scores range from zero to 100 with higher scores indicating greater function.[26]

Specific outcomes after arthroscopy were commonly measured using three instruments: the WOMAC, the Lequesne Index and AIMS-2. The WOMAC is a well-validated and reliable instrument to measure clinically important changes in health status after surgical intervention. It consists of 24 items in both a five-point Likert scale and 10 cm visual analog format. The Lequesne Index is a validated patient-reported index measuring pain, discomfort, maximum distance walked, and activities of daily living. This index is scored from 0 to 24 with scores over fourteen indicating severe handicap.[27] AIMS-2 is a health status questionnaire to assess function, work, social support, and problems due to arthritis. It consists of a seventy-eight item questionnaire with twelve scales and has been validated and found to be reliable in arthritis patients.[28]

B. Discussion of evidence reviewed

Identification of relevant clinical evidence

Compilation of the body of evidence for lavage and debridement for osteoarthritic knees involved searching the following databases for systematic reviews, study protocols, and peer-reviewed publications in the following databases:

- Cochrane Systematic Reviews
- NHS Center for Reviews and Dissemination (DARE, NHS, EED, HTA)
- ACP Journal Club Online
- PEDro
- ECRI
- CMA Databases

- BCBS-TEC
- ICIS
- RAND
- MJA
- NICE
- SIGN
- GRAYLIT
- NHS CRD
- Netting the evidence
- MTPPI
- INAHTA
- Bandolier
- Medline

In addition, Clinical trials.gov was searched for ongoing clinical trials of relevance.

The following combinations of terms were used to search the databases mentioned above:

#1 Osteoarthritis and arthroscopy and knee
#2 Debridement and lavage and osteoarthritis and knee and arthroscopy.
#3 Debridement and lavage and osteoarthritis and knee

Articles were included if they were written in English, peer reviewed, contained >10 cases, examined a patient population with painful osteoarthritis of at least one knee at the start of the study, and performed arthroscopy with debridement or lavage or both.

Articles were excluded if they were abstracts or review articles, focused solely on non-debridement arthroscopic procedures such as abrasion arthroplasty, treatment for traumatic or non-traumatic meniscal tears or cruciate ligaments alone, or treatment for other mechanical knee pain.

Search of the various databases, using the aforementioned search strategy, and articles submitted by AAOS resulted in 100 articles. After reviewing the abstracts of these articles, 26 articles were found to be consistent with the criteria described and were included in our appraisal. The following section provides a synthesis of the clinical evidence for arthroscopic lavage and debridement by each health outcome of interest. Appendix B provides, in chronological order, a summary of all the literature that met selection criteria outlined above. For each article, the purpose of the study, characteristics of the population, study design, key outcomes, and results are summarized. A discussion of the strengths and weaknesses of these articles and their relevancy to the Medicare population can be found in the CMS Analysis section.

Clinical evidence of the impact of arthroscopic lavage alone for osteoarthritis of the knee

The synthesis of the evidence surrounding lavage alone sought to answer the following question:

> *Is the evidence adequate to determine the impact of arthroscopic lavage alone on reduction of pain and improvement of function?*

Three articles examined the relationship between pain and lavage alone.[29] These three studies were randomized controlled trials (RCTs). An additional randomized controlled trial conducted by Moseley et al (2002) also addressed the question of lavage alone compared to a placebo along with debridement. The results of this trial are summarized in the following section in order to avoid repetition.

Dawes et al (1987), a randomized treatment study of 20 consecutive patients with OA, compared the benefits of joint lavage and simple saline injection. The primary outcome was walking pain, as measured by a visual analog scale (VAS). Results showed an initial difference between the experimental and control groups at week one, but by week four, there was no significant difference in pain while walking. Authors concluded that two-liter saline washout (experimental group) conferred no more benefit than ten milliliters intra-articular saline injection (control), and that "saline washout has no role in the management of OA of the knee."

Ravaud et al (1999) conducted a multicenter, prospective RCT to evaluate the efficacy of joint lavage and intra-articular steroid injection, both alone and in combination, in patients with symptomatic knee OA. The primary outcome was percent change in severity of pain evaluated on a visual analog scale. A positive outcome was defined as at least a 30% change in VAS. Ninety-eight patients were randomized into four treatment groups: intra-articular placebo, intra-articular steroid, intra-articular placebo plus joint lavage, intra-articular steroid plus joint lavage. By week 24the last week of data collection, those receiving lavage had a significantly greater change in pain compared to those receiving placebo (36% vs. 2%, p=0.02) or steroid injection (21% vs 2% placebo, p=0.31). However, there was no significant improvement in function as measured by Lequesne's functional index after week 24, regardless of assigned treatment.

Kalunian et al (2000) was a multi-center, double-masked, RCT with 90 participants. The aim of the study was to determine whether full-volume saline lavage versus minimal-volume saline lavage changes clinical and functional outcomes in patients with early knee osteoarthritis. The primary outcome was change in aggregate WOMAC score. The study showed no significant difference in aggregate WOMAC scores between patients receiving full -volume saline lavage or minimal-volume saline lavage.

In summary, these studies demonstrated that patients receiving lavage alone might have a short-term reduction in pain; however, this benefit was not persistent. In addition, none of these studies reported an improvement of functional status with lavage.

Clinical evidence of the impact of arthroscopic debridement for osteoarthritis of the knee

The synthesis of the evidence surrounding debridement sought to answer the following question:

> *Is the evidence adequate to determine the impact of arthroscopic debridement on decreasing pain and improving function?*

Thirteen articles examined the relationship between pain and debridement.[30] While many different scales were used (Appendix 1), the most common measures used to assess pain included the WOMAC, SF36, AIMS2, HSS, and other unvalidated scales.

Most studies showed a positive result, where at least 50% of participants experienced some combination of decreased pain or increased function. The results ranged from no change in outcome[31] to 74% of patients with reduced pain or increased function.[32]

Three randomized studies showed no statistically different change or reduction in pain in patients receiving debridement.[33] Chang et al (1993) randomized 32 patients to either debridement or closed-needle joint lavage. There was no statistically significant difference in any of the clinical, functional or global outcomes between the debridement group and the lavage control group. Both groups reported improvement in pain at 12 months compared to the start of the study. However, no statistically significant difference in the outcomes existed between the debridement and lavage group.

Gibson et al (1992) randomized 20 patients to either lavage or debridement with osteophyte removal. The primary outcome was muscle strength in the affected quadriceps compared to muscle strength in the non-affected quadriceps. Muscle strength was a proxy for improved knee function, with the assumption that with improved knee mobility and use, the quadriceps muscle strength would improve from its pre-surgical measurement. The authors found no significant improvement in muscle strength or function of the affected leg for those randomized to either group.

The most rigorous study identified in the literature addressing health outcomes from arthroscopic lavage alone and debridement was a study conducted by Moseley et al (2002). This study was a RCT designed to evaluate the effectiveness of both lavage and debridement on the reduction of pain and improvement of functioning for those with painful osteoarthritic knees refractory to medical management. This study was the first of its kind to independently evaluate the resulting health outcomes from both lavage and debridement compared to a placebo. In addition, this study was considerably larger than past studies and enrolled 180 patients into three armsplacebo surgery (n=60), debridement (n=59), and lavage (n=61).

Patients were eligible for the study based upon their self-report of moderate knee pain (greater than or equal to four as measured by a 10mm VAS) despite maximal medical treatment for six months. Other inclusion criteria were age 75 years or younger, OA of the knee as defined by the ACR, , and no arthroscopy in the last two years. The primary outcome was knee pain at 24 months which was assessed by the KSPS. At year one, there were no statistically significant differences in pain score between patients receiving debridement (51.7% vs 48.9%; p=0.51) or lavage (54.8% vs 48.9%; p=0.14) compared to the placebo group. These findings for pain were reflected in results of the AIMS-2, where no statistically significant differences existed between those receiving debridement or lavage compared to placebo.

The results of this study showed that arthroscopic lavage and/or debridement in patients with osteoarthritis of the knee without other specific indications is no better than placebo surgery in reducing pain and improving function.

Hubbard (1996), an RCT, compared arthroscopic debridement with lavage in 76 patients with clearly defined levels of degeneration of the articular cartilage of the medial femoral condyle. The primary outcome was pain and symptom relief. Of note, no menisectomy was done. Success or failure was determined by denoting the absence or presence of pain. The mean improvement by modified Lysholm was 28 for the debridement group at one year and 21 at five years. There was a significant difference between the debridement and lavage groups at one year, with 32 of the debridement group and five of the lavage group reporting no pain (p=0.05).

Of the thirteen studies evaluated, eight were case series addressing the net health outcome of pain.[34] Most of these showed a positive result. These case series had methodological problems that will be discussed in section VI. Of these case studies, Sprague (1981) showed the greatest magnitude of benefit for the reduction of pain post-debridement. Sprague (1981) (n=78) was a case series of one surgeon to determine if debridement is an effective alternative to maximal medical management of OA and delays time to TKR. The primary outcome was patient-reported functioning pre- and post-surgery. Fifty-one patients (74%) reported “good” results.[35] “Fair” results,[36] were reported by 10% (n=7) of patients. Finally, 16% (n=11) reported “poor” results.[37] The remainder of these case series results are summarized in the evidence table (Appendix B).

Clinical evidence of the impact of arthroscopic lavage or debridement for subpopulations of patients with osteoarthritis of the knee

The synthesis of the evidence surrounding debridement sought to answer the following question:

Is the evidence adequate to determine the impact of either debridement or lavage for a subpopulation of those with OA?

The goal of this section of the review was to identify whether there was a sub-group of patients who clearly did or did not benefit from lavage or debridement.

Patients with severe OA

Seven articles suggest that a subpopulation of patients with OA exists who do not improve with debridement and lavage and for whom this procedure is not appropriate.[38] These patients are those with severe OA, commonly characterized as those with Outerbridge classification III-IV articular degeneration. As described in Appendix B, these studies consistently report that those with severe OA had worse outcomes post-debridement. Of these seven articles, six were case series and one used a comparison group.[39]

Bonamo (1992), the most methodologically sound study design, was a retrospective, unmatched case-control. The goal was to determine prognostic factors for patients over 40 undergoing arthroscopic partial menisectomy and limited debridement of coexisting degenerative articular surface erosion. The control group did not have clinically significant articular degeneration. Of the 246 participants, 181 completed the study and were divided into two groups related to severity of Outerbridge classification. Those with Outerbridge classification I&II were in Group I (n=63) and the more severe were in Group II (Outerbridge III&IV, n=118). Patient satisfaction was a measured outcome. Patients in Group II with more severe arthritis were less satisfied with their results.

OA Patients with mechanical symptoms[40] in addition to pain

Four articles examined the impact of debridement on patients reporting mechanical symptoms in addition to pain. Based on these studies, it is suggestive that patients with OA who report mechanical symptoms in conjunction with pain may benefit from debridement. A case series study by Linschoten (1997) (n=68) addresses mechanical symptoms as a secondary outcome measure and shows no predictive relationship between improvement and mechanical symptoms. Whereas, Yang (1995) (n=103), another case series, suggests that preoperative mechanical symptoms are predictive of a good outcome. Two other case series, Baumgaertner et al (1990) (n=49) and Ogilvie-Harris et al (1991) (n=57) used subjective, unvalidated scales to measure patient satisfaction and improvement following surgery for patients reporting mechanical symptoms. These studies showed that at least 50% of participants improved following the procedure. Olgilvie-Harris et al (1991) showed an 82% success rate (defined as the percentage of patients who felt their knee symptoms improved post surgery) immediately after the surgery, with this result falling to 50% at three years post surgery.

Additional evidence

Evidence-based guidelines

The AAOS has developed guidelines for the management of the osteoarthritic knee.[41], [42] Before arthroscopy is considered, patients must have a known diagnosis of knee OA and incapacitating instability, deformity, or pain with failure of maximal medical management, and meet several other criteria. The patient must not have a neuropathic joint,[43] no previous knee infection or osteomyelitis, no significant joint space loss, and no suspicion of avascular necrosis. If these conditions are met, arthroscopic debridement may be considered.

Furthermore, in a patient with internal derangement and a clear diagnosis of a loose body with primarily mechanical symptoms[44] or an unstable meniscal tear, debridement with lavage may be considered appropriate treatment. Finally, debridement of unstable meniscal tears and chondral injuries may relieve mechanical symptoms of catching, grinding, locking, or snapping.

These guidelines highlight the fact that results of arthroscopic debridement are variable, but high success rates are reported when there is no gross malalignment or instability, some articular cartilage remains, and symptoms are well localized. AAOS guidelines state that abrasion or drilling has not been shown to have any added benefit.

Professional Society Position Statements

American Academy of Orthopaedic Surgeons (AAOS)

AAOS believes there is a subset of patients who may be helped by arthroscopy; that with proper selection, patients with early degenerative arthritis and mechanical symptoms can derive significant benefit from arthroscopic surgery. There are a number of well-established indicators for arthroscopic debridement in patients with osteoarthritis of the knee, which include mechanical symptoms, limb and knee joint alignment, and severity of arthritis (with less severe OA having better outcomes).

It is well recognized in the orthopaedic community that pain alone is not a specific indicator for arthroscopy. AAOS, American Association of Hip and Knee Surgeons (AAHKS), Arthroscopy Association of North America (AANA), American Orthopaedic Society of Sports Medicine (AOSSM), and the Knee Society have reported to CMS that they educate their members to recognize that unless there are specific indicators in addition to pain, arthroscopic debridement is not recommended for patients with osteoarthritis of the knee. Finally, arthroscopic lavage is not indicated for the treatment of knee osteoarthritis.[45]

American College of Rheumatology (ACR)

CMS asked ACR for comments on their previous guideline, *Recommendations for the Management of Hip and Knee Osteoarthritis*, published in September 2000. The ACR maintains that routine arthroscopic lavage with or without debridement should not be routinely recommended to patients with knee osteoarthritis who have failed medical therapy. Arthroscopic removal of debris may, however, be useful for relief of pain and improvement in joint function in patients with mechanical symptoms due to loose bodies and meniscal tears. Further studies in these types of patients are needed.[46]

Expert Opinion

No other expert opinions outside of the meetings with professional societies described above were received.

Public Comments

CMS received letters from three physicians[47] during the public comment period. In general, the comments encouraged continued coverage for arthroscopy for the treatment of osteoarthritic knees in carefully selected patients. They noted flaws in the Moseley article which they contend limit its validity and usefulness, (e.g., the use of a nonconventional scoring system to assess knee pain and the disproportionately large number of male subjects in the study).

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

As mentioned previously, CMS reviewed 26 articles to understand the impact of arthroscopic lavage and debridement on the osteoarthritic knee. Much of the evidence available to draw conclusions were from case series,[48] which limit the conclusions regarding the effectiveness of lavage and debridement in reducing pain and improving function. Moseley et al (2002) provided the strongest methodological basis for inferring the impact of lavage and debridement on pain for a selected group of patients.

The following section describes our analysis of the results found in the articles appraised and their relevancy to our determination of reasonable and necessary for the Medicare population. The goal of this final section is to provide discussion of the strengths and weaknesses of the body of evidence used to draw conclusions for our determination. Each of the questions chosen for our decision are addressed in this manner.

Is the evidence adequate to determine the impact of arthroscopic lavage alone on reduction of pain and improvement of function?

Five articles reviewed examined the impact of lavage alone. Key outcomes from the evidence reviewed consistently demonstrate that arthroscopic lavage for the treatment of the osteoarthritic knee does not reduce pain or improve knee function.[49] While these studies all had some limitations, they each followed a randomized controlled study design and, when reviewed as a whole, the consistency of their results supports the conclusion that arthroscopic lavage alone is not effective for these purposes. Weaknesses of Dawes et al (1987) include small sample size and the fact that the selection and randomization processes were not fully described. Weaknesses of Ravaud (1999) include the fact that 23/98 of randomized patients withdrew due to ineffective procedure or were lost to follow-up. Kalunian et al (2000) failed to use a placebo for comparison to lavage. We found no studies that indicated a positive effect for lavage alone in patients with osteoarthritis in comparison to a control group receiving no surgery or only placebo surgery.

CMS concludes that the number of consecutively treated patients published throughout the literature, the consistency of the findings across studies, and the magnitude of clinical improvements observed on validated and unvalidated scales have provided adequate evidence that lavage alone is not reasonable and necessary for the treatment of OA. In addition, the studies reviewed addressing this question included randomized controlled trials. CMS does not expect these results to differ for the Medicare population because most of the studies included patients near or at Medicare age. Furthermore, orthopedic professional societies believe that the scientific evidence and clinical consensus clearly indicates that lavage alone is not indicated under any circumstances for the arthroscopic management of OA of the knee.

Is the evidence adequate to determine the impact of arthroscopic debridement on pain and improvement of function?

Thirteen articles examined the impact of arthroscopic debridement on decreasing pain. Four of these studies were randomly controlled trials (RCTs) that enrolled study populations reflective of the Medicare population. Three of these RCTs found no reduction in pain[50] and only one[51] found a reduction in pain. We discuss our analysis of these studies in more detail below. The remaining eight studies were case series and suffered from small sample sizes and limited internal validity. While these case series studies generally showed a positive benefit for pain, methodological problems in these studies limit their utility in demonstrating the effectiveness of arthroscopic debridement for patients with pain only.

Weakness of Chang et al (1993) (n=32) and Gibson et al (1992) (n=20) were that they were small, unmasked, and did not use a placebo arm. However, the RCT design makes these results somewhat informative.

Moseley, et al. (2002) concludes that for patients with painful OA of the knee refractory to medical management, debridement and lavage was not shown to be effective. The weaknesses of this study include possible selection bias where 144/324 (44%) refused participation, a lack of women enrolled relative to their risk of OA, and failure to conduct intention- to- treat analyses. However, patients were randomized into treatment groups and bias was limited by this process. In addition, the primary outcome was knee pain at 24 months and was assessed by the KSPS, a previously unvalidated scale. However, the secondary outcomes were measured by validated instruments, which suggest effects in the same directions (AIMS2-P, SF-36-P, AIMS2-WB, SF-36-PE, PFS). Despite these weaknesses, this study represents the best level of evidence due to its size (which allows for increased generalizability), the use of a placebo or sham arm, use of randomization, masking of participants and assessors, the use of clinically relevant outcomes, and the long follow-up (24 months).

CMS concludes based on the strength of the evidence from Moseley et al (2002) and consistency with previous RCTs and case series that debridement is not found to be reasonable and necessary for the treatment of OA in patients presenting with pain alone. CMS does not expect these results to differ for the Medicare population because most of the studies addressing debridement included patients near or at Medicare age. Furthermore, orthopedic professional societies also believe that the scientific evidence and clinical consensus clearly indicate that debridement for pain alone is not indicated under any circumstances for the arthroscopic management of OA of the knee.

Is the evidence adequate to determine the impact of debridement and lavage alone for a subpopulation of those with OA?

Seven articles suggest that a subpopulation of patients with severe OA exists who do not improve with debridement and lavage and, for whom, this procedure is not appropriate.[52] All but one of these studies were case series, which are not considered to be reliable evidence for drawing conclusions. Bonamo (1992) used a comparison group and found that patients with severe OA had poorer results from lavage and debridement procedures than those with less severe OA. Additionally, orthopedic experts do not recommend this procedure in patients with severe OA.[53]

CMS concludes adequate evidence exists that lavage and debridement is not found to be reasonable and necessary for the treatment of patients with severe OA (Outerbridge classification III-IV). Again, CMS does not expect these results to differ for the Medicare population because most of the studies addressing debridement included patients near or at Medicare age. Orthopedic professional societies strongly believe that the scientific evidence and clinical consensus clearly indicates that debridement and lavage for severe OA is not indicated.

While some evidence suggests that there may be subpopulations with other osteoarthritic conditions for which debridement could be effective in reducing pain and improving function, our review found that evidence to be inconclusive because of methodological deficiencies. In three of four studies addressing debridement in patients with mechanical symtoms as the indication for surgery, the patients reported improvement in pain and function.[54] However, all were case series with no control group and used unvalidated assessment scales. More rigorous evidence on the benefit of debridement for patients with OA and experiencing mechanical symptoms does not currently exist. While agreeing that the existing level of evidence data for debridement in decreasing mechanical symptoms is suboptimal, the three case series consistently suggest clinically relevant improvement in outcomes. Additionally, though Moseley et al (2002) is the only large scale, well-designed RCT in the pool of evidence, it does not specifically address the issue of reduction of mechanical symptoms; therefore, its results do not refute or support possible benefit to subpopulations, which may exist.

In the absence of stronger evidence demonstrating the impact of arthroscopic debridement on the subpopulation of patients who do not have severe osteoarthritis (Outerbridge classification III or OV), and who present with symptoms other than pain alone, CMS will not issue a national coverage determination for this subpopulation. Determination of whether such coverage is reasonable and necessary will remain at contractor discretion.

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1 Arthritis Foundation: www.arthritis.org/conditions/DiseaseCenter/oa.asp on January 13, 2003 , National Center for Health Statistics website: www.cdc.gov/NCHS/faststats/arthritis on Jan 14, 2003

2 NIAMS, www.niams.nih.gov/hi/topics/arthritis/oahandout.htm on January 13, 2003

3 Harrison’s Principles of Internal Medicine, Fourteenth edition, 1998, pp 1939-1941

4 Medicare pays 80% of allowed charges. ICD-9 715.06-715.16, 715.26, 715.36, 715.96 cross-referenced to CPT 29870, 29871, 29874-29883

5 NIAMS, www.niams.nih.gov/hi/topics/arthritis/oahandout.htm on January 13, 2003

6 Harrison's Principles of Internal Medicine, Fourteenth edition, 1998, pp 1939-1941

7 Chronic inflammation leading to a type of scaring of the bone

8 Bone spurs are the growth of cartilage and bone at the joint margins

9 NIAMS, www.niams.nih.gov/hi/topics/arthritis/oahandout.htm on January 13, 2003

10 Altman R, et al.: *Development of Criteria for the Classification and Reporting of Osteoarthritis*, Arthritis Rheum 29:1039, 1986 for the ACR

11 Reduction of joint load via weight loss, rest, walking aids, physical therapy

12 Acetaminophen and nonsteroidal anti-inflammatory drugs

13 ACR website: www.rheumatology.org/patients/factsheet/oa.html January 13, 2003

14 Where the bone is cut to alter alignment and shift weight bearing stress

15 Where a diseased, damaged, or ankylosed joint is reconstructed, by natural modification or artificial replacement

16 Hubbard (1996)

17 Removal of hypertrophied synovium

18 Partial removal of torn mobile fragments of the medial and/or lateral menisci, a type of padding in the knee (AAOS)

19 removal of damaged and loose areas of articular cartilage in order to achieve a stable surface AAOS

20 http://www.thephysiotherapysite.co.uk/knee/age_risks_followup.html accessed on March 10.

American Academy of Orthopedic Surgeons (AAOS) 2002: Improving Muscoskeletal Care in America (IMCA) Project: Osteoarthritis of the Knee, Chicago, Report

21 Individual's subjective experience of discomfort which may be acute, chronic, localized or diffuse.

22 Functioning may include ability to walk, run, stand, bend, climb stairs, perform activities of daily living.

23 Outerbridge (2001)

24 Gallagher (2001)

25 Kosinski (1999)

26 Lysholm and Gillquist (1982)

27 Lequesne (1997)

28 Meenan (1980)

29 Kalunian (2000), (Ravaud) 1999, (Dawes 1987)

30 Dervin (2003), Moseley (2002), Shannon (2001), Harwin (1999), McGinley (1999), Linschoten (1997), Yang (1995), Chang (1993), Timmoney (1990), Sprague (1981), Hubbard (1996), Wouters (1992), Ogilivie-Harris (1991)

31 Moseley (2002), Chang (1993), Gibson (1992)

32 Sprague (1981)

33 Moseley (2002), Chang (1993), Gibson (1992)

34 Dervin (2003), Shannon (2001), Harwin (1999), McGinley (1999), Linschoten (1997), Yang (1995), Timoney (1990), Sprague (1981), Wouters (1992)

35 equally functional or more functional than prior to surgery

36 defined as some improvement that was less, equal, or more functional than prior or no noticeable improvement but more functional than prior

37 defined as unchanged or worse symptoms or needing subsequent surgery

38 Wouters (1992), Olgilivie-Harris (1991), Fond (2002), Bonamo (1992), Rand (1985), Shannon (2001), and Linschoten (1997)

39 Bonamo (1992)

40 mechanical symptoms include, but are not limited to: locking/snapping/popping

41 AAOS, department of research and scientific affairs, Knee Pain-Phase II (Specialty), Version 1.1, 1997, page 2-3, weblink: http://www.aaos.org/wordhtml/pdfs_r/guidelin/chart_05.pdf on March 13,2003

42 AAOS, department of research and scientific affairs, Knee Pain-Phase I, version 1.0, 1996, page 2, weblink: http://www.aaos.org/wordhtml/pdfs_r/guidelin/chart_04.pdf on March 13, 2003

43 marked destruction and instability with only mild degree of symptoms

44 internal derangement, the following findings being consistent with diagnosis: locking/snapping/popping, worsens with activity, better with rest, intermittent, crepitation, joint line tenderness, lack of full ROM, positive meniscal compression, joint line swelling

45 AAOS Arthroscopic Surgery and Osteoarthritis of the Knee. A Report to CMS-CAG, December 2002

46 ACR website: http://www.rheumatology.org/research/guidelines/oa-mgmt/oa-mgmt.html

47 William L. Healy, MD, Lahey Clinic; David R.Diduch, MD, University of Virginia; and Dennis M. Smith, MD, Peer Review Network, Inc.

48 Dervin (2003), Shannon (2001), Harwin (1999), McGinley (1999), Linschoten (1997), Yang (1995), Timoney (1990), Fond (2002), Bonamo (1992), Wouters (1992), Ogilivie-Harris (1991), Baumgaertner (1990), Rand (1985),

49 Hubbard (1996), Ravaud (1999), Dawes (1987), Kalunian (2000), Moseley (2002)

50 Moseley (2002), Chang (1993), Gibson (1992)

51 Hubbard 1996

52 Wouters (1992), Olgilivie-Harris (1991), Fond (2002), Bonamo (1992), Rand (1985), Shannon (2001), and Linschoten (1997)

54 Yang (1995), Ogilivie-Harris (1991), Baumgartner (1990)

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